



Wyeth Pharmaceuticals
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February 25, 2004

Mr. John Becher
Centers for Disease Control/Drug Service, D-09
1600 Clifton Road
Atlanta, GA 30333

COL John D. Grabenstein, RPh, Ph.D
Deputy Director for Military Vaccines
U.S. Army Medical Command
5111 Leesburg Pike (Suite 401)
Falls Church, VA 22041-3258

Re: STN 101106 - Smallpox Vaccine, Dryvax®


Dear Mr. Becher and COL Grabenstein:

Please note that Wyeth received approval on February 25, 2004 for BLA Supplement STN 101106/5044 to extend dating of Lot 4020071 of Smallpox Vaccine, Dryvax® from 24 to 30 months. The new expiration date is August 2004.

Additional testing in accordance with the protocol filed to our license will be conducted and a CBE supplement will be submitted to extend the expiration dating beyond 30 months, if appropriate.

Please note that the storage period of the vaccine after reconstitution with diluent continues to be 90 days.

Sincerely yours,


Dennis J. Foley, Ph.D.

DJF:jm